Minutes of the Third meeting of the RNTCP DOTS Plus Committee held on 17 January 2006 at Nirman Bhavan, New Delhi

The meeting was held on 17 January 2006 from 1030 hrs onwards in the Committee Room, Room no. 249 A-Wing, Nirman Bhavan, New Delhi. The list of participants is annexed at Annexure-I.

DGHS, Dr R. K. Srivastava, addressed the meeting and referred to the good progress made by the RNTCP which has made it an internationally acclaimed programme. He acknowledged the contribution the members of the committee were making to the process of development of treatment guidelines for MDR-TB by the Government of India and thanked the Committee members for contributing their valuable time for the same.

DDG(TB) after welcoming the expert group, laid out a rough plan on how to proceed on the DOTS Plus Implementation. The National Programme would aim to initiate the first patient on DOTS Plus treatment on or around the first of October 2006. DDG also informed that two meetings of a smaller sub-committee (Writing group) had met at Central TB Division on two occasions in the interim, on 22nd November 2005 and 20th December 2005 and had written up and refined two draft versions of the RNTCP DOTS Plus guidelines. He thanked the Writing Committee for their inputs in such a short time-frame. What is available now is the second draft which would be reviewed by the larger RNTCP DOTS Plus Committee and finalized. After this meeting, Central TB Division would circulate the pre-final version of the guidelines and comments need to be send by the members of the Committee in a week's time, after which the guidelines would be finalized. He also informed that the Technical Specifications Committee for RNTCP DOTS Plus drug procurement has been constituted by the Ministry of Health and Family Welfare, GoI, and was scheduled to meet on 18 January 2006 to finalise the technical specifications for RNTCP second-line anti-TB drugs which the programme would procure in due course.

The proceedings of the Committee were as recorded below:

- DDG(TB) informed that the RNTCP's Lab Committee meeting which was held on the previous day (16 Jan 2006) had made a strong recommendation to the Central TB Division to remove the chapter on infection control from the DOTS plus guidelines and just to have a brief note on the same in the chapter on lab aspects. It was felt that as infection control was an issue of the state health systems, and RNTCP was a small constituent of the health systems, we may not highlight infection control over and above basic services like treatment and care. The DOTS Plus infection control guidelines would be a part of the overall RNTCP infection control guidelines and are recommended to be adopted by the state health systems. The DOTS Plus Committee unanimously agreed to the proposal.

- The issue of exclusion of pregnant women/ paediatric populations from treatment under MDR-TB in special situations was discussed. It was felt that the population groups which were being excluded such as pregnant women and children would need to be included in the ambit of the programme at some time. DDG(TB) assured that this issue would be taken up once the DOTS Plus implementation became more widespread. For the piloting we may continue with the existing agreed to exclusion criteria.

- Later, with regard to the chapter on treatment of MDR TB in special situations, it was decided that the teratogenic effect of second-line anti-TB drugs in pregnant women was seen only in the first trimester and therefore it was decided to exclude pregnancy in women patients of reproductive age, offer family planning advice for the entire duration of treatment and delay treatment till after first trimester based on severity of illness in pregnant women patients. When therapy is started, three or four oral drugs with demonstrated efficacy against the infecting strain should be used, and then reinforced with an injectable drug and possibly other drugs be given immediately postpartum. The committee felt that post-partum, such patients should nurse the baby as long as she is sputum negative. The treatment should try to achieve sputum conversion before parturition in case of smear positive pregnant women patients.

- The Committee decided to continue with the earlier definition of MDR-TB Suspect. The definition of the outcome of cure was debated. At this juncture it would be important to keep the DOTS Plus guidelines in line with International definitions as far as possible. But the Committee felt that a modification of the international definition may be appropriate in the Indian context. Therefore the outcome of cure was defined thus: "*An MDR-TB patient who has completed treatment and has been consistently culture negative (with at least 5 consecutive negative results in the last 12 to 15 months). If one follow-up positive culture is reported during the last three quarters, patient will still be considered cured provided this positive culture is followed by at least 3 consecutive negative cultures, taken at least 30 days apart, provided that there is clinical evidence of improvement*". It was also decided that the date of registration would be used to determine the cohort to which the patient would belong. Cohorts would be quarterly cohorts.

- Initial referral of MDR-TB suspect may be from MO-PHI (peripheral level) and not MO-TC (TU level) to the DTC.

- Regarding laboratory aspects, the Committee sustained the earlier meeting decisions that Conventional culture using egg based media will be used. DST will be done using Proportion method. The drugs tested for will be INH, Rifampicin, Streptomycin and Ethambutol. Presently only the regional WHO Supra-national Reference Lab, namely TRC Chennai has the capacity to carry out second-line anti-TB drug sensitivity testing, but such capacity may be developed over a period of time in other NRLs. The Lab experts on the committee presented a document

for the Accreditation of IRLs under RNTCP, which would form the basis of External Quality Assurance for labs doing culture and sensitivity in the country. This needs to be approved by the Central TB Division in due course along with ratification by the Lab Committee.

- The SOPs for culture and sensitivity testing which had been prepared as a training manual for lab staff was also presented before the Committee by the Lab experts from Tuberculosis Research Centre (TRC), Chennai and National TB Institute (NTI) Bangalore, for further approval by Central TB Division after review by other experts.

- Keeping in view the RNTCP Phase II project's capacity in providing resources, the Committee took the view that the provision of drugs for about two years for each patient and the provision of daily DOT would be the substantial part of treatment of MDR-TB and these would be well-covered and resourced under the National programme. The ancillary drugs for management of side effects and Clinical lab investigations should be provided by the state health systems. State commitment to offer these services to the population was an integral component of the DOTS Plus programme. The national programme will not financially support the non-mycobacterial lab investigations and clinical investigations of MDR-TB patients. The DOTS Plus programme would be closely integrated into the DOTS Programme. The decision on the site of the State DOTS Plus indoor facility should be taken based on availability of all required lab and radiological investigations at that centre. Biochemical investigations including serum electrolytes, radiological investigations including X-ray and ultrasound facilities and histopathological investigations should be available at the chosen site. Preferably, the site should also be in close proximity to an RNTCP accredited Intermediate Reference Lab (IRL).

- The Committee cast doubts on the need for an extension of Intensive phase of treatment of under DOTS Plus. Tuberculosis Research Centre (TRC), Chennai citing their experience so far mentioned that 90% of patients who respond to MDR-TB treatment respond in the first three months of treatment and the value of providing extension of the Intensive phase for another 2 to 3 months is very doubtful. No data is available in-country on the same. However Dr. Wares from WHO India suggested that the country guidelines should be in line with international guidelines as far as possible and as the international guidelines suggested extension of IP in patients not responding to treatment, we may retain the proposed system of having extension for those patients not responding to treatment.

- The Committee agreed that the weight bands to be retained as it is, but for the issue of change over across weight bands, it was suggested that there should be change over to the higher weight band when patient gains more than 5 kgs and crosses the weight band.

- The example of the DOTS Plus Programme in Nepal was quoted where antacids were being routinely offered to patients along with the drugs. However since H2 inhibitors can affect absorption of certain drugs in the regimen, it was decided that antacids/ proton pump inhibitors/ H2 blockers will not be offered routinely to patients. Therefore, omeperazole need not be procured at the Central level.

- It was decided to have a para on prophylaxis removed as there were no clear international guidelines for the same internationally too. The precautions for Health Care Workers (HCW) is not for TB only, it is for other diseases too. The contact tracing for sputum positive MDR-TB patients will be the same as contact management for drug susceptible sputum positive DOTS cases under RNTCP guidelines and there will be no special contact tracing for MDR-TB.

- The Committee took the view that since the RNTCP's routine honorarium for community DOT providers at Rs 250 per patient cured seemed inadequate for the DOTS Plus community volunteers who would provide daily DOT for 2 years to patients, Central TB Division should have an enhanced rate of honorarium for DOTS Plus community DOT providers in the range of Rs. 800 to Rs. 1000 per year per provider per patient on treatment. These patients were expected to be very few and therefore it is not expected to be a significant amount for the project. The Committee also suggested that patients themselves would be under severe financial strain due to loss of work and based on humanitarian considerations, some provision of financial support should be provided to patients, for example, reimbursement of travel expenses to DTC and State DOTS Plus indoor facility.

- The Committee reviewed all the recording and reporting forms. The Referral for treatment form was presented and minor changes were suggested and incorporated in the other forms. It was decided not to have a separate "Referral for Ambulatory treatment form" as the "Referral for treatment form" will suffice for both purposes. Decisions were taken on where each document was to be kept and if duplicate/ triplicate copies were maintained how the original would be updated was discussed. The Committee recommended that the Initial Physical Evaluation data need not be a part of the National Programme's data collection and should be looked at by the Hospital DOTS Plus Committee only. Therefore only a shortened Initial evaluation checklist for patients was retained, as compared to the previous draft.

- The Committee decided not to recommend the system of having patient-wise-boxes for drugs in the initial years of DOTS Plus under RNTCP as the patient numbers would be very few. Thereafter, based on experience, Central TB Division may modify the system of packaging drugs for patients.

- Some of the Committee members suggested that there should be a system of evaluation of patients two years after cure/ treatment completion. A consensus was reached that such evaluation need not be done as a routine, but after the first

two cohorts of outcomes the programme may have some operational research on this topic.

- The Committee debated whether the constitution of the DOTS Plus Committee at the State level and at DOTS Plus site should be pre-determined under the DOTS Plus Guidelines based on official designation. After debating the issue, it was decided not to have a fixed constitution for the DOTS Plus Committee at this juncture. The Committee suggested that after the experience from the pilot sites in Maharashtra and Gujarat, Central TB Division may make changes or issue new instructions for such Committees accordingly. However the Committee agreed that presence of State TB Officer on both the State DOTS Plus Committee and the DOTS Plus site Committee is mandatory to avoid administrative deficiencies in the working of these two Committees.

List of participants of the Third meeting of the RNTCP DOTS Plus Committee held at 249-A, Committee Room, Nirman Bhavan, New Delhi on 17 January 2006:

1. Dr L. S. Chauhan, DDG (TB)
2. Dr. P. R. Narayanan, Director, TRC Chennai
3. Dr. S K Sharma, Chairman, National Task Force for Involvement of Medical Colleges under RNTCP
4. Dr. Prahlad Kumar, NTI Bangalore
5. Dr C N Paramasivan, Senior Deputy Director, TRC Chennai
6. Dr. Rohit Sarin, Medical Supdt, LRS Institute, Delhi
7. Dr. A. B. Patil, State TB Officer, Maharashtra
8. Dr. S K Jain, Chairman, Zonal Task Force (West Zone)
9. Dr. Rajendra Prasad, Chairman, State Task Force, Uttar Pradesh
10. Dr. R N Solanki, Chairman, State Task Force, Gujarat
11. Dr. K R John, Chairman, Zonal Task Force (South Zone)
12. Dr Shantadevi Sethumadhavan, WHO Consultant, TRC Chennai
13. Dr. Rajeshwari Ramachandran, Deputy Director, TRC Chennai
14. Dr M. S. Jawahar, Deputy Director, TRC Chennai
15. Dr V P Myneedu, Microbiologist, LRS Inst., New Delhi
16. Dr Balasangameshwara, CMO, NTI
17. Dr. Rupak Singla, CMO, LRS Institute
18. Dr. Ranjini Ramachandran, Assistant Director, TRC Chennai
19. Dr Ritu Gupta, TB Specialist, Central TB Division
20. Dr Ajay Thirumala, Consultant Microbiologist, NTI Bangalore
21. Dr. Fraser Wares, WHO-India
22. Dr. S. Sahu, WHO-India
23. Dr. Yamuna Mundade, RNTCP Consultant, Central TB Division
24. Ms. Kavitha Nair, Strategic Alliance Management Division, Central TB Division